UNITED STATES DISTRICT COURT
DISTRICT OF NEBRASKA

Civil File: 4:16-cv-03086-JMG-CRZ

Stephanie Ideus,

Plaintiff,

AMENDED COMPLAINT AND JURY DEMAND

vs.

Teva Pharmaceuticals USA, Inc., and Teva Women's Health, Inc.,

Defendants.

Plaintiff Stephanie Ideus, by and through the undersigned attorneys, for her Complaint and causes of action against Defendants above named states and alleges as follows:

PARTIES

1. Plaintiff Stephanie Ideus is a resident of the State of Nebraska, residing in Martell, Nebraska.

2. Defendant Teva Pharmaceuticals USA, Inc. is a Delaware Corporation with its principal office located at 1090 Horsham Road, North Wales, PA 19454, and a registered agent for service of Corporate Creations Network, Inc., 3411 Silverside Road, #104, Rodney Building, Wilmington, DE, 19810.

3. Defendant Teva Women's Health, Inc. is a Delaware Corporation with its principal office is located at 41 Moores Road, Malvern, PA 19355, and a registered agent for service of Corporate Creations Network, Inc., 3411 Silverside Road, #104, Rodney Building, Wilmington, DE, 19810.

JURISDICTION AND VENUE

4. Jurisdiction is founded upon 28 U.S.C. § 1332 because there is diversity of citizenship between the parties and because the amount in controversy exceeds seventy-five thousand ($75,000) Dollars, exclusive of costs and interest.

5. Pursuant to 28 U.S.C. § 1391(b)(1) and (2), venue in this District is appropriate because the defendants are subject to personal jurisdiction in this district and maintain contacts in this district sufficient to subject them to personal jurisdiction, and because a substantial part of the events giving rise to the claim occurred in this district.

ALLEGATIONS

6. At all relevant times the Defendants through their agents, servants, and employees, designed researched, manufactured, labeled, packaged, promoted, marketed and/or sold the ParaGard Intrauterine Device ("ParaGard").

7. At all times relevant, the Defendants engaged in extensive mass media direct-to-consumer promotion, education and advertising of ParaGard for the purpose of increasing sales and stimulating consumer requests for Paragard independent of the advice of medical professionals.

8. Defendants knew that ParaGard can and does cause serious harm to individuals who use it through undetected breakage while implanted or breakage while being removed.

9. Defendants knew of the of these dangerous risks from the trials they performed, their post-marketing experience and complaints, third party studies, and their own analysis of these studies, but took no action to adequately warn or remedy the defects and instead concealed, suppressed, and failed to disclose this danger.

10. On January 11, 2010, Plaintiff underwent a procedure to have a ParaGard inserted at Planned Parenthood of Nebraska and Council Bluffs.

11. On or about July 14, 2014, her physicians attempted to remove the ParaGard and found that it had broken into at least two pieces, resulting in an incomplete removal of the ParaGard and leaving the broken arm of the ParaGard within her.

12. Subsequently, Plaintiff presented to several health professionals to determine if the broken arm of the ParaGard could be removed. Initially, hysteroscopy and vigorous dilation and curettage were preformed but the broken arm could not be located or retrieved.

13. Eventually, ultrasound found that the ParaGard had embedded deep in the uterus, in the posterior cervix deep within the myometrium. Physicians noted that it was not something one could see or palpate. Hysterectomy was recommended as a way of removing it. The Paragard was ultimately surgically removed on February 12, 2015 at the Mayo Clinic without hysterectomy.

14. The ParaGard was marketed heavily by the Defendants as safe and effective, promising fewer side effect than other birth control methods.

15. The marketing and promotion efforts of the Defendants, their advertisers, and sales force serve to overstate the benefits of ParaGard, and minimize and downplay the risks associated with the ParaGard. These promotional efforts were made while Defendants fraudulently withheld important safety information from the physicians and the public.

16. The product warnings for ParaGard were vague, incomplete or otherwise wholly inadequate, both substantially and graphically, to alert prescribing physicians and patients to the actual risks associated with the ParaGard.

17. Not only have the Defendants failed to disclose in their labeling and

advertising that ParaGard is actually a dangerous birth control device, the Defendants have represented and continue to represent that safety is their first concern. For example, the Teva website states that:

> Quality and safety are our first priority. At the very heart of Teva's mission is our commitment to develop and manufacture high quality, safe products that promote global good health and well-being. Unwavering amidst rapid growth and widespread global enterprise, Teva continues to fulfill its commitment to the pursuit of uncompromising quality. We accept nothing but the highest attainable quality and safety standards and equally demand the same high standards from our suppliers and distributors worldwide.

18. The Teva website also assures physicians and patients that Teva's longstanding track record of quality and safety assurance relies on four fundamental principles:

1. Constant re-examination and re-evaluation of processes: We foster and cultivate quality and safety throughout the entire manufacturing process, thereby ensuring a consistently high quality of product. We strive for continuous improvement in all areas of our organization.

2. Commitment to meeting regulatory requirements: In all our facilities and at all stages of product life cycle, we are committed to meeting all applicable regulatory requirements.

3. Training: Teva's employees participate regularly in quality and safety certification programs as well as in the relevant GXP (Good Clinical Practice, Good Laboratory Practices and Good Clinical Practices) training.

4. Ongoing Pharmacovigilance: We maintain an Adverse Event Report database and employ drug safety officers to ensure compliance with global regulations. Furthermore, we follow special safety monitoring procedures for both our un-marketed and marketed products.

19. Based on these representations, upon which Plaintiff relied, including the omission from the ParaGard labeling of the danger of undetected breakage and breakage during removal, Plaintiff had the ParaGard inserted believing that it would be safe and effective.

20. The packaging provided with the ParaGard warned physicians and patients of several possible risks, including the risk of embedment and perforation. Both of these warnings were made in the context of a whole, non-broken, ParaGard either embedding in the myometrium, perforating the uterine wall or cervix during placement (described as a "rare" occurrence), or spontaneously migrating. NO WARNING THAT THE PARAGARD MAY BREAK WAS GIVEN IN THE WARNINGS SECTION.

21. The packaging provided with the ParaGard warned physicians and patient of certain "Adverse Reactions." Again, these included "perforation" and "embedment." NO WARNING THAT THE PARAGARD MAY BREAK WAS GIVEN THE ADVERSE EVENT SECTION.

22. The packaging provided with the ParaGard provided physicians and patients with instructions on "Continuing Care." These "Continuing Care" instructions stated that the threads of the ParaGard should remain visible, although their length may change. The instructions stated that "if you cannot find the threads in the vagina, check that the ParaGard is still in the uterus. The threads can retract into the uterus or break, or ParaGard can break, perforate the uterus, or be expelled." This was the first mention of possible ParaGard breakage in the packaging and was clearly tied to the threads not being able to be found. There was NO WARNING THAT THE PARAGARD COULD BE BROKEN IF THE THREADS COULD BE FOUND IN THE VAGINA. In other words, based on the statement in the

"Continuing Care" portion of the packaging, there was no reason for a patient to believe that there could be undetected breakage of the ParaGard, i.e., that if the threads could be found in the vagina, the ParaGard could be broken. Plaintiff had the threads checked several times by her health providers, including just two to three months before attempting to have the ParaGard removed, and her health providers were always able to find the threads of the ParaGard in her vagina, including right up to the time she attempted to have the ParaGard removed on or about July 14, 2014.

23. The packaging provided with the ParaGard provided physicians with instructions on placement and removal. The removal instructions stated that "embedment or breakage of the ParaGard in the myometrium can make removal difficult." Again, there was NO WARNING THAT THE PARAGARD COULD BE BROKEN IF THE THREADS COULD BE FOUND IN THE VAGINA.

24. As a direct result of Plaintiff's use of the ParaGard, Plaintiff suffered from having a broken arm of the ParaGard in her, causing her damage, including but not limited to pain, suffering, mental anguish, the risk of reproductive health complications, loss of the enjoyment of life, medical expenses and other out-of-pocket losses, and loss of income.

FIRST CAUSE OF ACTION
(NEGLIGENCE)

25. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

26. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of ParaGard

into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

27. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of ParaGard into interstate commerce in that Defendants knew or should have known that using ParaGard created a high risk of unreasonable, dangerous side effects, including, undetectable breakage of the ParaGard, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life.

28. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing ParaGard without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing ParaGard without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not ParaGard was safe for use; in that Defendants herein knew or should have known that ParaGard was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling ParaGard without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, and the medical and healthcare profession of the dangers of ParaGard;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, ParaGard;

(g) Failing to test ParaGard and/or failing to adequately, sufficiently and properly test ParaGard;

(h) Negligently advertising and recommending the use of ParaGard without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that ParaGard was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that ParaGard had equivalent safety and efficacy as other forms of birth control;

(k) Negligently designing ParaGard in a manner which was dangerous to its users;

(l) Negligently manufacturing ParaGard in a manner which was dangerous to its users;

(m) Negligently producing ParaGard in a manner which was dangerous to its users;

(n) Negligently assembling ParaGard in a manner which was dangerous to its users;

(o) Concealing information from the Plaintiff in knowing that ParaGard was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, her physicians, and the healthcare community concerning the severity of risks and dangers of ParaGard compared to other forms of birth control.

29. Defendants under-reported, underestimated and downplayed the serious dangers of ParaGard.

30. Defendants negligently compared the safety risk and/or dangers of ParaGard with other forms of birth control.

31. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of ParaGard in that they:

(a) Failed to use due care in designing and manufacturing ParaGard so as to avoid the aforementioned risks to individuals when ParaGard was used;

(b) Failed to accompany their product with proper and/or accurate warnings regarding possible adverse side effects associated with the use of ParaGard, including breakage that could not be detected by loss of threads;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of ParaGard, including breakage that could not be detected by loss of threads;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning ParaGard, including breakage that could not be detected by loss of threads;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(f) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of ParaGard;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of ParaGard, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

32. Despite the fact that Defendants knew or should have known that ParaGard caused unreasonably dangerous side effects, Defendants continued and continue to market, manufacture, distribute and/or sell ParaGard to consumers, including Plaintiff.

33. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

34. Defendants' negligence was the proximate cause of Plaintiff's injuries, harm and economic loss.

35. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous personal injuries including physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

36. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

37. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

38. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed ParaGard as hereinabove described that was used by the Plaintiff.

39. Defendants' ParaGard was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

40. At those times, ParaGard was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

41. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of ParaGard.

42. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective in design and/or formulation, in that, when it left the hands of the Defendants, manufacturers, and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

43. At all times herein mentioned, ParaGard was in a defective condition and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants.

44. Defendants knew, or should have known that at all times herein mentioned, their ParaGard was in a defective condition, and was and is inherently dangerous and unsafe.

45. At the time of the Plaintiff's use of ParaGard, ParaGard was being used for the purposes and in a manner normally intended, namely as a form of birth control.

46. Defendants, with this knowledge, voluntarily designed their ParaGard in a dangerous condition for use by the public, and in particular the Plaintiff.

47. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

48. Defendants created a product unreasonably dangerous for its normal, intended use.

49. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was manufactured defectively in that ParaGard left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users.

50. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' ParaGard was manufactured.

51. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular; and Defendants are therefore strictly liable for the injuries sustained by the Plaintiff.

52. The Plaintiff could not, by the exercise of reasonable care, have discovered ParaGard's defects herein mentioned and perceived its danger.

53. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings or instructions, as the Defendants knew or should have known that the product created a risk of serious and dangerous side effects including, undetectable breakage, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendants failed to adequately warn of said risk.

54. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate warnings and/or inadequate testing.

55. The ParaGard designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects including undetectable breakage, as well as other severe and permanent health consequences from ParaGard, they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product, ParaGard.

56. By reason of the foregoing, Defendants have become strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, ParaGard.

57. Defendants' defective design, manufacturing defect, and inadequate warnings of ParaGard were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

58. Said defects in Defendants' ParaGard were a substantial factor in causing Plaintiff's injuries.

59. As a result of the above described defects, Plaintiff was caused to suffer serious and dangerous personal injuries including physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

60. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

61. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

62. Defendants expressly warranted that ParaGard was safe and well accepted by users.

63. ParaGard does not conform to these express representations because ParaGard is not safe and has serious side effects, including undetectable breakage, that were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

64. Plaintiff did rely on the express warranties of the Defendants herein such that those warranties formed a part of the basis of the bargain between Plaintiff and Defendants.

65. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of ParaGard in recommending, prescribing, and/or dispensing ParaGard.

66. The Defendants herein breached the aforesaid express warranties, as the ParaGard was defective.

67. Defendants expressly represented to Plaintiff, Plaintiff's physicians, and/or healthcare providers that ParaGard was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of birth control, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

68. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that ParaGard was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

69. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous personal injuries including physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

70. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

FOURTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

71. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

72. The Defendants falsely and fraudulently represented to the medical and healthcare community, to the Plaintiff, and to the public in general, that said product, ParaGard, had been tested and was found to be safe and/or effective as a form of birth control.

73. That representations made by Defendants were, in fact, false.

74. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

75. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, ParaGard.

76. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used ParaGard, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

77. In reliance upon said representations, Plaintiff was induced to and did use ParaGard, thereby sustaining severe and permanent personal injuries.

78. Defendants knew and were aware or should have been aware that ParaGard had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

79. Defendants knew or should have known that ParaGard had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

80. Defendants brought ParaGard to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

81. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous personal injuries including physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

82. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

FIFTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

83. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

84. Defendants had a duty to represent to the medical and healthcare community, to the Plaintiff, and to the public in general that said product, ParaGard, had been tested and found to be safe and effective as a form of birth control.

85. The representations made by Defendants were, in fact, false.

86. Defendants failed to exercise ordinary care in the representation of ParaGard, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of

said product into interstate commerce, in that Defendants negligently misrepresented ParaGard's high risk of unreasonable, dangerous side effects.

87. Defendants breached their duty in representing ParaGard's serious side effects to the medical and healthcare community, to the Plaintiff, and to the public in general.

88. As a result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous personal injuries including physical pain and mental anguish, diminished enjoyment of life, and financial expenses for hospitalization and medical care.

89. As a result of the foregoing acts and omissions, Plaintiff has suffered and incurred damages, including medical expenses and other economic and non-economic damages.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determine at trial of this action;

3. Pre-judgment interest;

4. Post-judgment interest;

5. Awarding Plaintiff her reasonable attorneys' fees;

6. Awarding Plaintiff her reasonable costs of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

BENNEROTTE & ASSOCIATES, P.A.

Dated: September 2, 2016

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